

June 2, 1999

Dr. C.W. Jamison NTP Report on Carcinogens P.O. Box 12233 Research Triangle NC 27709

Dear Dr. Jamison:

The International Smart Tan Network hereby submits the following comments pertaining to the review process for the NTP's Tenth Annual Report on Carcinogens, and hereby requests to be included in all future public proceedings regarding this report. Our sole interest in this process is the possible inclusion of UVA, UVB and UVC – from either solar exposure or artificial light sources – in the Report. We feel such an inclusion is not warranted, is not in the spirit of such a list and will ultimately only serve to impede efforts to teach people proper sun care habits.

Our submission to you will be concise and to the point. Our organization just became aware of this comment process May 24, which gave our standing Federal Regulatory Review committee little time to prepare this document. We would, however, like to reserve the right to present further evidence for our case as the review process continues. Nevertheless, despite the short time we had to prepare this submission, we have made every effort to reveal the full nature of our position in this submission. Our submission is organized into the following sections:

#### 1.0 Introduction

- 1.1 The International Smart Tan Network Mission Statement
- 1.2 Smart Tanning Is Teaching Effective Sunburn Avoidance

#### 2.0. Our Position on Listing Ultraviolet Light as a Carcinogen

- 2.1 The Case for Inclusion is Built on Half-truths
- 2.2 No Known Dose-Response Rates for Skin Cancer from UV Light
- 2.3 Should a Ubiquitous Item Be A Carcinogen?
- 2.4 Positive Effects of UV Outweigh the Negative For Those Who Can Tan
- 2.5 The Photoprotective Tan

#### 3.0 Conclusion

UV Light Should Not Be Listed As a Carcinogen, Because it is Ubiquitous

Questions or comments about this submission can be addressed to Smart Tan executive director Joseph Levy, 3101 Page Avenue, Jackson MI 49203, or phone 517-784-1772, ext. 12.

#### 1.0 INTRODUCTION

## 1.1 International Smart Tan Network Mission Statement:

Dedicated to educating indoor tanning professionals and the millions of customers they serve, the International Smart Tan Network is a synergetic worldwide consortium of thousands of tanning professionals committed to researching and promoting the responsible, life-long skin-care regimen of moderate suntanning for individuals who can develop a tan and sunburn avoidance for all. The International Smart Tan Network is an educational organization representing nearly 20,000 professional indoor tanning facilities in the United States, Canada, Australia and New Zealand. More than 3,000 facilities are full members of the association, while an estimated 15,000 other facilities use Smart Tan training materials to train their employees and teach their customers the concepts of smart tanning. Additionally, more than 20,000 indoor tanning facilities receive Smart Tan's monthly educational trade journal, Tanning Trends magazine, which has been published monthly since 1985, for the primary purpose of educating indoor tanning facility owners on protocol and correct operations and procedures designed to maximize the safety of their clients.

Redefining the standards of professionalism in the indoor tanning salon industry, Smart Tan and its members are committed to the following objectives:

- Teaching millions of tanners worldwide how to maximize the potential benefits of sun exposure while minimizing the potential risks associated with either too much or too little sunlight.
- Encouraging both tanners and non-tanners to examine the scientific research supporting the benefits associated with sun exposure, while at the same time respecting the potential risks.
- Supplying indoor tanning professionals with new and unparalleled educational opportunities to further their understanding of ultraviolet light and the tanning process.
- Raising consumer expectations of what constitutes a professional indoor tanning facility.
- Funding new scientific research on the positive effects of ultraviolet light and promoting this emerging field of evidence in its proper context, respecting benefits and risks.

Facilities are taught to implement what is known as The Smart Tan Creed: Moderate indoor tanning — <u>for individuals who can develop a tan</u> — is the smartest way to maximize the potential benefits of sun exposure while minimizing the potential risks associated with either too much or too little sunlight.

#### 1.2 Sunburn Prevention:

The bottom line of our message is summed up quite simply in what we call The Golden Rule of Smart Tanning: Don't *ever* sunburn.

Tanning facilities are playing a lead role in teaching the American public effective sunburn prevention habits. It is estimated that as many as 28 million Americans patronize tanning facilities at least once during each year, and the industry has witnessed steady growth since its American inception in the late 1970s.

Much of that growth is directly related to the realization that a tanning salon tan can play a role in helping tanners prevent sunburn during southern vacations. Indeed, the onset of the tanning industry's "busy season" from February through June is fueled by pre-vacation tanners who are tanning to build up resistence in their skin to the intense sub-tropical sun.

This massive amount of anecdotal data is indisputable. A 1997 Smart Tan Network survey of 4,000 indoor tanning customers in the United States provided further verification that tanning salons are helping to prevent sunburn. In the survey, 81 percent of tanning facility patrons indicated that they sunburn less often than they did before they began tanning in a salon. Smart Tan attributes this remarkable figure to two primary factors:

1) A tanning salon tan is photoprotective. While the amount of photoprotection gained in a tanning facility is not quantified, millions of cases every year provide sufficient anecdotal evidence that indoor tanning – combined with appropriate usage of sunscreen outdoors on vacation – can help an individual who has the ability to tan to prevent sunburn on a sun-filled vacation.

2) Tanning facilities are teaching the proper usage of sunscreen. Tanning facilities are in a unique position to communicate with the population that is most likely to tan outdoors and counsel them on the appropriate usage of sunscreen. We believe this is becoming more of a factor as the tanning facility industry grows.

It is our belief that by teaching both tanners and non-tanners how to avoid sunburn and overexposure to ultraviolet light, we will ultimately help them reduce their risks of permanent skin damage while maximizing the benefits they accrue from regular sun exposure.

# 2.0 OUR POSITION ON LISTING ULTRAVIOLET LIGHT AS A CARCINOGEN

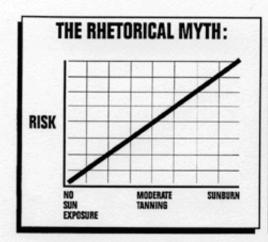
The International Smart Tan Network believes it would be a mistake to list ultraviolet light as a carcinogen in the NTP's Tenth Annual Report on Carcinogens for the following reasons:

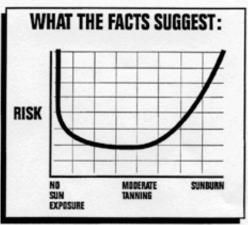
#### 2.1 The Case for Inclusion is Built on Half-Truths:

Anti-tanning lobbyists have made the statements that "There is no such thing as a safe tan" and that "Any tan is a sign of damage." <u>Unfortunately, both of these statements, without further qualification, are terribly misleading.</u>

2.11 "There is No Such Thing As a Safe Tan": In fact, the statement that "There is no such thing as a safe tan" is a semantic deception because the antithesis of that statement is also not true. Avoiding sunlight completely isn't safe either. In fact — because avoiding sunlight carries risks, as does getting too much sunlight — there is no such concept as "safe" when it comes to sunlight. The best we can possibly do is minimize the risks inherent with either too much or too little exposure.

The graphs on the following page illustrate our point. The left graph shows the conventional thinking about sunlight, what "sun-scare" lobbyists have drilled into our heads for more than a decade: that totally eliminating sun exposure eliminates risks. That is why "sun scare" lobbyists tell us to wear sunscreen 365 days a year, no matter where we live. But the right graph is a more accurate, albeit more complicated, description of the risk function. The one thing we do know for certain about sunlight is that zero exposure does NOT equal zero risk; in fact, the risks of zero exposure would be deadly. So the risk function *must* be curved. The vertex of that curve — where risk is minimized — is different for every person and cannot be randomly defined. Anti-tanning lobbyists want to define it for you anyway.





Therein lies the essence of our objection to what we call the "sun scare" campaign: Human life is totally reliant on sun exposure, and the life-giving effects of ultraviolet light. The question for each of us — a question that nobody knows the exact answer to — is how much sun exposure is appropriate, and how much is too much. Basing the answer to that question on the belief that any exposure increases one's risk of skin damage — a belief that is not categorically supported in the medical literature — is naive and fails to recognize the positive influence ultraviolet light and sunlight have on our lives.

New research on breast cancer, melanoma and other deadly diseases — research that shows that regular sun exposure may play a key part in preventing the onset or retarding the growth of these deadly diseases — supports the position that moderate sun exposure, for those of us who can develop a tan, is the best way to maximize the benefits of sun exposure while minimizing the risks of either too much or too little exposure.

That is exactly why the professional tanning industry uses the word "smart" to describe moderate tanning today. The word "safe" implies that one can recklessly abuse something without any fear of causing harm. And that certainly is <u>not</u> what we are trying to say. In fact, we are playing a key part in preventing that kind of reckless abuse. For example, previous generations believed that sunburn was an inconvenient but necessary precursor to developing a tan. Today we know better, and are teaching a new generation of tanners how to avoid sunburn at all costs. Again, our position: That moderate tanning is the best way to maximize the benefits of sun exposure while minimizing the risks of either too much or too little exposure.

2.12 "Any Tan is a Sign of Damage": As for the semantic deception that "Any tan is a sign of damage," we remind you that the body is a marvelous machine that is designed to damage itself in many ways as a natural course of action. For example, one who exercises to build strong muscle tissues knows that they body builds stronger muscles only by tearing tiny muscle fibers – the natural "repair" process is actually the way to build stronger muscles. On the surface, that can technically be called damage. But the word damage is not an accurate description of what is going on.

Similarly, the tanning process is the body's natural protection against sunburn and overexposure. The body's natural design is to repair any "damage" accrued in the process. To call this natural process damage is more misleading than it is accurate.

2.13 Skin Cancer Incidence Numbers Lack Pathological Confirmation: In the past five years estimates for the number of skin cancer cases in the United States have ranged from 400,000 cases reported each year to 1.2 million cases – a 300 percent variance. Part of the problem is that these estimates are not based on verifiable figures. There is no national tumor registry for skin cancer. Non-melanoma skin cancer cases are not listed by the American Cancer Society in its annual count of invasive tumors. It is our understanding that the majority of these tumors are never pathologically confirmed, and that the pathology in those that are biopsied is seldom done independently. Since there is the potential for bias when the pathology is done within the dermatology discipline, and because the diagnosis of skin cancer is somewhat subjective, as biologically benign lesions are often mis-classified as skin cancers on initial diagnosis (Penn State University dermatology professors Donald P. Lookingbill and James G. Marks, Jr., in their book, "Principles of Dermatology," cite one study that showed two-thirds of pigmented lesions clinically thought to be melanoma turned out to be benign pigmented lesions by histopathologic criteria) it is the position of the International Smart Tan Network that a better accounting of skin cancer incidence needs to be established before any policy decisions resulting from the prevalence of this disease can be made.

# 2.2 You Cannot Prove Dose-Response Rates for Skin Cancer from UV Light:

Categorically listing any form of UV light as a carcinogen would give the public the impression that any exposure to sunlight increases an individual's risk of contracting skin cancer—a statement that cannot be supported by scientific research, is not "practical" and ultimately is not believable. Because ultraviolet light is natural and because some ultraviolet light exposure is necessary for life to survive, categorically labeling this life-giving energy as carcinogenic may ultimately undermine the credibility of the rest of the work done by the Report.

. ISTN believes that the facts clearly show that is it inaccurate and misleading to "lump" UVR together for purposes of this discussion. We believe that the following classifications should be used:

UVC ..... Wavelengths from 100 to 280 nm.

UVB ..... Wavelengths from 280 to 315 (or 320) nm.
UVA-2 ..... Wavelengths from 315 (or 320) to 340 nm.

UVA-1 ..... Wavelengths from 340 to 400 nm.

It is the position of the International Smart Tan Network (ISTN) that inadequate evidence exists to warrant listing UVB, UVA-2 and UVA-1 as carcinogens – either as a "known carcinogen" or "reasonably anticipated to be a human carcinogen." To categorically list UV light as a carcinogen would mislead the public about the role heredity and other substances play in the development of skin cancer, and would further add to the confusion about carcinogenesis in the different forms of skin cancer.

# 2.21 Carcinogens And Cocarcinogens:

<u>Carcinogens</u> are defined by ISTN as "any cancer-producing substance that has the power, ability or tendency to produce cancer." When the word "carcinogen" is used, it encompasses both "known to be a human carcinogen" and "reasonably anticipated to be a human carcinogen" unless otherwise stated.

Co-carcinogens are defined by ISTN as "Agents that increase the effect of another carcinogen by direct concurrent effect."

2.21.1 <u>UVC</u>: UVC is not emitted in measureable dosages by equipment used by the indoor

tanning industry. Furthermore, little, if any, UVC reaches the surface of the earth. Therefore, we see little reason to classify UVC as a carcinogen. Doing so would only foster the wrong impression that people are exposed to this energy.

2.21.2. UVB: There is no credible evidence linking UVB to any form of skin cancer (SCC,

BCC and melanoma) as a carcinogen in humans.

2.21.3. <u>UVA-2</u>: There is no credible evidence linking UVA-2 to any form of skin cancer (SCC, BCC and melanoma) as a carcinogen in humans.

2.21.4. <u>UV-A1</u>: There is no credible evidence linking UVA-1 to any form of skin cancer (SCC, BCC and melanoma) as a carcinogen in humans.

2.22.1. Smart Tan believes that the following entities are known to act as cocarcinogens in conjunction with UVB (and possibly UVA-2), but not UV-A1 in humans.

> 2.22.1.1. . . . . Genetics. 2.22.1.2. . . . . Smoking 2.22.1.3. . . . Diet

2.22.1.4. . . . . Environmental Pollutants

2.22.1.5 . . . . Photosensitizing Drugs

2.22.2 The article "Half the truth is often a Great Lie" written by Donald L. Smith, was published in the February 1998 issue of *Tanning Trends* magazine and it covered, among other topics, the subject of co-carcinogens in the induction of skin cancer. All direct quotes from the article will be in quotation marks.

"When you read one of the many articles blaming ultraviolet radiation for causing skin cancer, it is implied the sun alone has carcinogenicity. If that were true, instead of "half the truth" we would see the same levels of skin cancer in all skin phototypes. And we know that phototype I individuals who are very sensitive to ultraviolet radiation get all three forms of skin cancer at much higher rates than do phototypes II, II, IV, V and VI. How could this be?"

"Today medical researchers recognize that many cancers, including skin cancer, are caused by multiple agents called co-carcinogens that can, in concert, cause cancer. Co-carcinogens are defined as "agents that increase the effect of another carcinogen by direct concurrent effect." The key word in the definition is "concurrent" and it helps to explain why phototype I individuals are more prone to develop all three types of skin cancer: basal cell carcinoma (BCC), squamous cell carcinoma (SCC) and melanoma.

GENETICS. "If you subject phototype I individuals who are genetically (constitutionally) very sensitive to either a high level of cumulative UVR or to many short episodes of acute levels strong enough to cause erythema (sunburn), the combination of the co-carcinogens, genetics and UVB radiation has been shown to increase the likelihood of developing skin cancer. Indeed, a phototype I individual is approximately seven times more likely to develop a melanoma, four times more likely to develop a basal cell carcinoma (BCC) and over twelve times more likely to develop a squamous cell carcinoma (SCC) than is a photo-protected individual. White et al in the report, "Case-Control Study of Malignant Melanoma in Washington State: Constitutional Factors and Sun Exposure" published in the May 1994 issue of the American Journal of Epidemiology showed the effect of consituitive (skin type) photoprotection and Armstrong and Kricker in their landmark paper, "Epidemiology of Sun Exposure and Skin Cancer," published in Cancer Surveys in 1996,

documented the photoprotective effect of both constituitive and facultative pigmentation."

"A piece of important evidence regarding the cocarcinogenicity of genetics and UVB radiation is the forced immigration experience of individuals of Celtic heredity from England and Ireland to Australia. The descendants of these immigrants are sun sensitive, fair-skinned individuals who sunburn easily and tan little or not at all and these individuals, that make up over half the Australian population, have one of the highest incidence of skin cancer in the world. Native Australians (Aboriginals) and those with higher levels of constitutive pigmentation and who are, therefore, more able to tolerate UVB radiation do not show significantly increased rates of incidence of skin cancer. It must be kept in mind when trying to compare skin cancer statistics between Australia and the United States that the land "down under" has approximately five to six times the percentage of sun sensitive individuals than we do in the USA and so one should not be surprised to find a higher incidence of skin cancer in Australia. Furthermore, one cannot use Australian incidence levels in comparisons with the United States without adjusting for the percentage of sun sensitive individuals."

SMOKING: "In the report 'A prospective study of incident squamous cell carcinoma of the skin in the nurses' health study' published in the July 1995 issue of Journal of the National cancer Institute, by Grodstein, Speizer and Hunter, the data showed that 'Finally, current cigarette smokers showed a 50% increase in the risk of SCC compared with never smokers." (3-5/28)

DIET: "A report in the international Jouirnal of Cancer in July 1995 titled 'Evidence that a low-fat diet reduces the occurrence of non-melanoma skin cancer' by Black et al from the Department of Dermatology, Baylor College of Medicine, Houston, Texas, provided evidence that diet is another cocarcinogen that must be considered in skin cancer. The authors stated that "These data indicate that a low-fat diet can significantly reduce (90% reduction in 24 months) ocurrence of a highly prevalent form of cancer." In a subsequent article published this year (1997) in Nutritional Cancer the same author concluded that "Practical dietary advice with respect to reduction of percentage of calories from fat, along with an increase in the intake of grains, fruits, and vegetables, could make an important contribution to the management and prevention of skin cancer."

ENVIRONMENTAL POLLUTANTS: "The Article "Skin Effects of air pollution" by L.A. Goldsmith of the Department of Dermatology, University of Rochester School of Medicine and Dentistry published in Otolaryngology, Head and Neck Surgery, stated that "In addition to being a target organ and site of neoplasms and contact allergens, the skin is the site of significant absorption of environmental pollutants. In the case of chloroform, the percutaneous absorption is equivalent to the respiratory uptake, emphasizing how important it is to recognize skin absorption in toxicologic exposures."

PHOTOSENSITIZING DRUGS: "Photochemotherapy with methoxsalen (psoralen) and high irradiance levels of ultraviolet A radiation (PUVA) has been shown to increase the incidence of squamous cell carcinoma, Merkel cell carcinoma and melanoma, presumably because of the tolerance lowering photochemical interaction between psoralen and DNA. Robert S. Stern, MD, and his colleagues at Beth Israel Deaconnes Medical Center and Harvard Medical School have written several articles documenting this unfortunate situation. It is thought that the psoralen drug used in PUVA therapy significantly lowers the erythemal threshold (tolerance) by amplifying the effect of the UVA photons, thereby acting as cocarcinogens. It took, however, between 15 and 20 years and over 250 PUVA treatments before the association between PUVA and skin cancer came to light. We estimate that it would take 75 to 100 years for an individual who tanned three to four times a week for 20 minutes each time to accumulate the same net effective irradience level as does a patient

receiving PUVA therapy for 15 - 20 years. The indoor tanning industry does not use psoralens in tanning lotions and, therefore, our clients are not subjected to the adverse photochemical reaction caused by the use of this powerful photosensitizing agent."

"The mechanism by with PUVA therapy is thought to induce skin cancer was covered in the Parrish et al paper, "Photochemotherapy of Psoriasis with Oral Methoxsalen and Longwave Ultraviolet Light" that was published in the December 5, 1974 issue of the New England Journal of Medicine." The authors stated that "The photosensitizing property of both methoxsalen (8-methoxypsoralen) and trioxsalen (4, 5', 8-trimethylpsoralen) is related to the ability of photoexcited psoralen molecules (triplet state) to transfer the absorbed ultraviolet energy to DNA. In this photochemical reaction, psoralen covalently binds to DNA, forming monofunctional single-strand photoadducts with thymine bases and interstrand cross links (bifunctional adducts) between opposite pyrimidine base pairs. The formation of these C4-cyclobutane photoadducts of psoralen and pyrimidines presumably leads to inhibition of DNA synthesis. This inhibition of epidermal DNA synthesis is the rationale for the use of psoralens in the treatment of psoriasis."

In summary, the Stern papers do not provide evidence related to the accumulation of exposure from ultraviolet tanning devices because psoralens are not administered to, nor used by, clients patronizing indoor tanning salons. Indeed, the cocarcinogenic PUVA problem belongs solely and completely to the dermatology community.

#### 2.23 Melanoma

It is the position of the International Smart Tan Network that insufficient evidence exists to make a causal association between ultraviolet light exposure and malignant melanoma skin cancer. What's more – because the research community agrees that the relationship between ultraviolet light and melanoma has not been defined, and because confounding evidence exists suggesting that regular ultraviolet exposure might actually be protective against melanoma for some skin types – it would be a mistake to classify UV light as a carcinogen based on melanoma arguments. Much more research is required before the true etitology of this disease is fully known and understood.

2.23.1 Confounding Evidence: The paper, "Melanoma is not caused by sunlight,"published in the journal Mutation Research by Allen J. Christophers, MD, identifies reasons why conclusions about the supposed association between ultraviolet light and melanoma are premature, and may in fact eventually prove to be erroneous. Dr. Christophers, a retired occupational medicine specialist, summarized the findings of his meta-analysis of 14 case-control studies which examined the relationship between melanoma incidence and total accumulated sun exposure as follows:

"The conclusion that can be drawn from looking at these studies as a whole is that melanoma is not due to sun exposure. Indeed the conclusion is so clear that it is difficult to understand why scientific consensus still clings to the idea that sunlight is a cause of melanoma."

The argument against sunlight being a cause of melanoma is best supported by comparing the distribution of melanomas on the body surface. In his meta-anlysis, Christophers points out: "If a skin cancer is due to sunlight, then its site density on the areas of the body more exposed to sunlight should be greater than its site density on the less exposed areas of the body, and the difference should roughly reflect the difference in accumulated sun exposure of these areas. The more exposed areas of the body are the neck, head, ears, and the backs of the hands, and these areas

constitute about 6 percent of the total skin area of the body and the less exposed areas constitute about 94 percent of the total area." Comparing the three categories of skin cancer in this respect is revealing. Consider that 87 percent of all squamous cell carcinomas (SCC) are found in the more exposed areas and 13 percent in the less exposed areas. For basal cell carcinoma (BCC) 83 percent occur on the more exposed areas and 17 percent occur on the less exposed areas. For melanoma, however, only 22 percent occur on the more exposed areas and 78 percent on the less exposed areas.

What's more, Christophers' points out that there is no more melanoma incidence in individuals who get regular sun exposure than in those who don't. That conclusion has been supported by other researchers. Dr Cedric F. Garland and Dr. Frederick C. Garland have published work showing that outdoor workers are less likely to contract melanoma than indoor workers, again offering confounding evidence as to the role of sun exposure in melanoma incidence.

2.23.2 <u>Tanning Lamp Usage and Melanoma:</u> A paper written by Drs. Anthony J. Swerdlow and Martin Weinstock titled "Do Tanning Lamps Cause Melanoma: An Epidemiological Assessment" that was published in the January 1998 issue of the *Journal of the American Academy of Dermatology* reviewed 19 articles claiming a "link" between tanning lamp use and melanoma. Swerdlow and Weinstock's conclusion was simple:

# "At this time, the published data <u>are insufficient</u> to determine whether tanning lamps cause melanoma."

Seven reasons why the 19 studies reviewed were not considered to be based on epidemiologically valid data were given by Swerdlow and Weinstock. (Statements with quotation marks around them are taken directly from the Swerdlow and Weinstock paper.)

Lack of Relevant Intensity and Output Data.

"The published studies gave no information on the intensity and spectral outputs of the tanning lamps to which exposure had occurred. Furthermore, because the prevalent type of lamp has changed over time, there is some uncertainty in extrapolation from historical exposure to exposure in the population today."

What this means is that the authors of the 19 studies reviewed did not account for the differences in sunbeds, lamps and exposure time and, therefore, that they could not calculate total irradience values. Also, the authors refer to the high UVB lamps used in the early days of the tanning industry, compared to the combinations (lamps) that are in use today.

#### Recall bias Potential.

"All of the studies depended on the recall of exposures by the study participants and this recall may potentially be biased." For example, many researchers believe patients with melanoma might exaggerate their past exposures or recall more of them than control participants. It is also possible that such a recall bias could affect the outcomes in other ways."

Studies Lack Specificity Regarding Exposure.

"Many of the studies reported only a comparison between persons who were ever exposed to tanning lamps and those who were never so exposed; or between undefined 'use' and 'non-use' of tanning lamps."

Failure to Control Lamp and Exposure Location Variables.

"Relatively few of the reports described their variables on tanning beds and the analyses of the date in detail or with precision. for example, some included medical in addition to cosmetic UV lamp espouse in their analyses, without distinction and others did not and for several reasons it was not clear whether medical exposure had been included. Ideally, both of these sources, and occupational exposures, would be included in the data collection and analysis."

Additionally, the authors write that one study "suggested that home exposure may be more closely associated with melanoma than commercial exposures, but the results were not conclusive." home tanners can tan as often and as long as they choose, but only one in the 19 studies examined suggested that tanning at home might cause melanoma. What's more, the authors of that paper stated that, "sunlamp use in commercial settings was not associated with subsequent development of melanoma."

#### Possibility of Confounding Errors.

"Interpretation is also complicated by the possibility of confounding. For instance, sun exposure - particularly recreational sun exposure - is a potential confounding variable because it seems likely that tanning lamp users may also be more likely to sunbathe. In addition, sun sensitivity (tolerance) and socioeconomic related factors are also potentially confounding variables."

#### Publication Bias.

"There may be a substantial publication bias in this area of literature. Case-control studies that support the null hypothesis (that tanning lamps are not associated with the later development of melanoma or that tanning might be beneficial) may be less likely to mention this aspect of their data or to describe in detail the resulting publication than those that found an association between sun bed use and melanoma.'

Furthermore, the authors stated that "based on the 19 studies reviewed herein, it does appear that those studies that were interpreted as "negative" were less likely to have published detailed analyses (e.g., on duration and age associations) than those with positive findings."

It is also probable that only articles critical of tanning lamps were even selected to be published, an additional example of publication bias.

#### Inadequate Sample Size.

"Many studies appear to have low power to detect a plausible size of association. In several instances, only a small proportion of the study population had used tanning lamps; therefore, the likelihood of finding a significant association will have been low, even if a real and strong association exists. However, even among those studies in which a substantial proportion of the participants had used tanning lamps, the real power depends on the proportion who had used them frequently enough, for a sufficiently long duration, far enough in the past, and perhaps at a sufficiently young age, for an effect of these exposures to be detectable epidemiologically. Existing studies can only give evidence on risks for types of exposure for which there now exist appreciable numbers of persons. For example, if the minimum period between the tanning lamp exposure and melanoma caused by it is two decades, it is doubtful whether any of the published studies to date would have sufficient power to detect a plausible size of effect of tanning lamp use on melanoma risk."

For these reasons, Swerdlow and Weinstock reached the following conclusion:

"At this time, the published data are insufficient to determine whether tanning lamps cause melanoma. Although most methodological concerns raised herein would tend to obscure a potential association between tanning lamp use and melanoma risk, some (recall bias, publication bias and confounding by sun exposure and socioeconomic-related factors) would tend to induce an artifactual association."

It should be noted that the paper "Use of sunbeds or sunlamps and malignant melanoma in southern Sweden" by Westerdahl et al that was published in the American Journal of Epidemiology (1994; 140:691-9) was one of the 19 articles reviewed by Swerdlow and Weinstock. Data provided by Swerdlow and Weinstock showed that the Westerdahl failed to control for sun exposure variables, sun sensitivity and sun damage, including sunburn and/or the presence of freckles. For this reason, this article cannot be used to support the position that tanning lamps have any role in the induction of melanoma.

#### 2.3 Should a Ubiquitous Element Be Called a Carcinogen?

It is the belief of the International Smart Tan Network that listing UV as a carcinogen would create more confusion in the effort to convince people of all skin types to avoid overexposure and sunburn. Because nothing in our lives is more pure and natural than sunlight, we project that the public will not only ignore such a mislabeling, but would also take less stock in the labeling of other substances by the NTP Report on Carcinogens.

Such a backlash would be unfortunate, not only in that it would be a set-back in legitimate attempts to teach people how to minimize the risks that may be associated with overexposure to sunlight, but would also undermine the believability of the rest of the list and the process that places such substances on the list.

It is noteworthy that the other candidates for inclusion in the Tenth Annual Report on Carcinogens include Beryllium compounds, Dimethoxybenzidine, Vinyl Bromide and Vinyl Flouride. To our knowledge, life is not supported by exposure to any of these items. But ultraviolet light is an essential component to life on this planet. Unilaterally classifying UV light as a carcinogen would be as impractical and misleading as classifying all air or water as a carcinogens because of substances that may be present in them. If the public is to be properly warned about the possibility of risks associated with overexposure to ultraviolet light, a blanket allegation that either intentionally or unintentionally indicts any UV exposure will only be counter-productive.

### 2.4 Positive Effects of UV Light Outweigh the Risks For Those Who Can Tan

The indoor tanning industry was not developed in the United States: It evolved in Europe as a means to accrue the biologically positive effects of regular exposure to ultraviolet light. That reality is often forgotten today in the United States when the merits of a cosmetic tan are discussed.

"Photobiology started around the positive effects of ultraviolet light. It is interesting that the detrimental effects of Photobiology get more attention than the positive effects. It is easier to study damage."

Dr. Jan van der Leun, professor of Photobiology at Utrecht University in the Netherlands, reminded a roomful of researchers at the National Institute of Health's three-day conference on ultraviolet light and skin cancer Sept. 16-18, 1998 of that fact. It is the position of the International Smart Tan Network that the beneficial effects of sensible, moderate, appropriate and responsible tanning far outweigh the minimal and controllable risks for all except skin phototype I individuals, who are not able to develop facultative pigmentation (better known as a "tan") and do not currently have any alternative other than to limit their exposure to the sun and to wear protective clothing and prudently use sunscreen when circumstances cause them to be in sunlight.

But what is wise to tell an individual with Type I skin – a classification that makes up less than 5 percent of the American population – is not wise to mandate across the board for our society

as a whole:

"On the basis of present knowledge the board agreed that campaigns aimed at stressing the danger of excessive sun exposure should be addressed to the <u>subjects at risk. Campaigns</u> addressed to the entire population should be discouraged."

This statement by the Advisory Board was published in the "European School of Oncology Advisory Report: Sun Exposure, UVA Lamps and Risk of Cancer" in the European Journal of Cancer in 1994 and it should be adopted intact by all appropriate agencies and departments in the United States Government and by dermatology industry lobbying groups. Failure to comply with this standard will compromise legitimate attempts to warn people about overexposure and sunburn when the public learns more about the positive effects of ultraviolet light exposure – a field of research that is once again emerging.

2.4.1 General Benefits Of Exposure To UV Light

The following observations were made by Zane R. Kime, MD, MS, in his book "Sunlight" (1980). Many are proven benefits of UV exposure, others are theories that lack proof but are plausible and supported by understood mechanisms.

- 2.4.11 <u>Destruction of Bacteria</u>. Downes and Blunt, in 1877 discovered the dramatic ability of sunlight to destroy bacteria.
- 2.4.12 <u>Tuberculosis</u>. In 1904, the Nobel Prize in physiology was awarded for Finsen's observation that sun exposure was therapeutic for tuberculosis. (Finsen, N.R. in Phototherapy (Edward Arnold Publishing, London, 1901) (10-1-5/31)
- 2.4.13 <u>Sunlight And Physical Fitness</u>. "It has been demonstrated that after a patient has been on a good endurance exercise program for several months, his resting heart rate begins to decrease (1); and it has also been demonstrated that a patient's resting heart rate will decrease and will return to normal much more rapidly following exercise, if he includes sunbathing in his physical fitness program (2)."
- (1) Skinner et al, "Effects of a Program of Endurance Exercises on Physical Work" American Journal of Cardiology (1964).
- Lehman & Szakal (German) Arbeitsphysiologie (1932).
- 2.4.14 <u>Respiratory Rate</u>. "Similarly, a patients respiratory rate not only decreases following an endurance exercise program, but it also decreases following sunbathing and the patient's breathing is slower, deeper, and seems to be easier." (3)
- (3) Laurens, H., "The Physiologic Effect of Ultraviolet Radiation" JAMA (1939)
- 2.4.15 <u>Lactic Acid Decrease</u>. "Less lactic acid accumulates in the blood during exercise following sunbathing, another effect which usually follows a course of physical training." (4)

- (4) Parade et al, (German) Z Klin Med (1939).
- 2.4.16 Oxygen content Of The Blood. "Sunlight seems also to increase the blood's capacity to carry oxygen and to deliver it to the tissues. A striking increase in the oxygen content of the blood has been shown to follow a single exposure to ultraviolet light. This effect lasts for many days." (5) (5) Miley, G, "Ultraviolet Blood Irradiation: Studies in Oxygen Absorption" American Journal of Medical Science (1939).
- 2.4.17 <u>Asthma</u>. "Severe, intractable bronchial asthma patients were able to breathe freely and the color of their skin returned to a normal pink following an ultraviolet light treatment." (6) (6) Seidel, R.E., et al: "Preliminary Report of Results Observed in Eighty Cases of Intractable Bronchial Asthma" Archives of Physical Therapy (1943).
- 2.4.18 <u>Pyogenic Infections</u>. "The blue color of a seriously ill patient suffering from peritonitis, paralytic ileus, and bronchial pneumonia, returned to a normal pink following an ultraviolet light treatment." (7)
- (7) Miley, G., "Ultraviolet Blood Irradiation Therapy in Acute Pyogenic Infections" American Journal of Surgery (1942).
- 2.4.19 Endurance. "Fatigue is a common complaint today, but contrary to feelings, more rest may not always be the best answer. As stated previously, a good exercise program decreases fatigue and increases the capacity for work. Marked improvement in one's endurance and working capacity has also been found to follow sunlight treatments (2). The fact that sunlight seems to increase oxygen in the tissues undoubtedly contributes to this effect. Another factor may be that glycogen (stored energy for the body) is increased in the liver and the muscles following sunbathing. (8) This would allow for the increased indurance observed."
- (8) Pincussen, L.: "The Effect of Ultraviolet and Visible Rays on Carbohydrate Metabolism" Archives of Physical Therapy (1937).
- 2.4.20 Increased Blood Supply. "Sunlight seems, also, to increase the blood supply to the deep internal organs and muscles (9). The skeletal muscles underlying the skin get an increased amount of blood when exposed to the sunlight (10). This is important in helping to develop muscular strength and will also help to prevent sore muscles when a new activity is undertaken."
- (9) Levy, M.: (German) Strahlentherapie (1919)
- (10) Bing, H.: "Effects of Ultraviolet Rays in Depth and Duration" Acta Medicine Scandinavia (1943).
- 2.4.21 <u>Testosterone</u>. "Another interesting point, relating to sunlight's effect on muscular strength, is the relation sunlight has to the male hormone, testosterone. The Greeks had an unusual practice called *arenation* exercising nude on a warm sandy beach. The reason the location was a sandy beach is that sand has a good reflective surface. This practice, they believed, developed the muscles to their maximum potential. It may well have, for as sunlight strikes the male genitals it stimulated the production of the male hormone, testosterone (11). Testosterone is responsible for the secondary male sexual characteristics: lowering of the voice, growth of the beard, and muscular development of the male physique. Its effect on muscle development and bulk has been recognized by athletes for years. They have periodically experimented with it in hopes of increasing the size and strength of their muscles. Sunlight striking any part of the male body stimulates the production of testosterone. It is when sunlight strikes the male genital area, however, that the greatest production of testosterone is realized (11).
- (11) Myerson & Neustadt: "Influence of Ultraviolet Irradiation Upon Excretion of Sex Hormones in the Male" Endocrinology (1930).

2.4.22 <u>Blood Pressure</u>. "Exercise can be of great benefit in lowering the blood pressure. In one study, twenty-three men who had high blood pressure were given a moderate exercise program. They did twenty minutes of calisthenics and thirty to thirty-five minutes of jogging twice a week. After six months on the program, they averaged an 8% drop in their blood pressure (12). In another study, six hundred and fifty-six men who had high blood pressure were given a more vigouous program of exercise. It was found that these men had an average reduction in their blood pressure of 15% (13).

A study done at Tulane University, on the effect of ultrviolet light on blood pressure, showed that men, who had normal blood pressure, had a slight lowering that lasted one or two days following a single exposure. At the same time, a group, that had high blood pressure, had a marked lowering of the blood pressure, that lasted five or six days (14). It would seem, therefore, that a good exercise program, combined with a sunbathing program, would go along way towards eliminating hypertension in this country."

(12) Boyer & katsch: "Exercise Therapy in Hypertensive Men" JAMA (1970).

(13) Hellerstien, H.: "A Primary and Secondary Coronary Prevention Program," in Raab, W (editor) Prevention of Ischemic Heart Disease (1966).

(14) Johnson, J., et al: "The Effect of Carbon Arc Radiation on Blood Pressure and Cardiac Output" American Journal of Physiology (1935).

2.4.23 The Heart's Efficiency Increases. "A good endurance exercise program will not only lower the pulse rate, but will also increase the efficiency of the heart, allowing it to pump more blood at each beat, and also allowing the heart more time to rest between beats. Sunbathing can also increase the efficiency of the heart. In one study, the output of blood from the heart was increased by an average of 39% in the group of patients studied. The increased output continued for five or six days following a single ultraviolet light exposure (14). Physicians use drugs to stimulate the heart, causing it to pump more blood. These drugs could possibly be eliminated in some cases if the patient were to follow an active exercise program out-of-doors in the sunlight."

2.4.24 <u>Blood Sugar Decreases</u>. "Exercise will lower the blood sugar in a diabetic and enable the diabetic require less insulin or medication (15). Exercise also helps those with hypoglycemia (low blood sugar) by stabilizing their blood sugars and keeping them from dropping to the point where they experience alarming symptoms."

"Exposure to sunlight appears to have an insulin-like effect in that it causes a lowering of blood sugar. This is minimal in normal individuals, but dramatic in diabetics (8, 16). When blood sugar drops in diabetics, it is manifested by a reduction of sugar in the urine. Blood sugar is lowered by a process in which some sugar is revoved from the blood and is stored in the muscles and liver as glycogen, thus by increasing its glycogen stores, the human body can reduce its blood sugar. This process can apparently be achieved by the sun's stimulating enzymatic reactions in the body. Initially, the sunlight stimulates and increase of the enzyme phosphorylase. Phosphorylase decreases the amount of stored glycogen. After a few hours an enzyme called glycogen synthetase starts to increase. This enzyme increases glycogen storage in the tissues while decreasing blood sugar levels. This effect continues and reaches its maximum level in about ten hours (17)."

"A high level of glycogen means that the body has enough reserves of energy to supply prolonged physical exercise. From this it can be seen that it would be best to take part in strenuous exercise on the day following exposure to the sunlight. A single suberythema dose of sunlight produces this effect and it may last several days."

"Because of this dramatic effect, a diabetic may need to adjust his insulin dose when he is

following a sunbathing program. Because sunlight combined with insulin can have a very powerful hypoglycemic effect, a diabetic must sunbathe with caution. By gradually increasing the exposure to sunlight and decreasing the dose of insulin, one may avoid a hypoglycemic reaction. A diabetic who chooses to sunbathe should always keep in touch with his physician, who can best determine his need for insulin."

(15) Cooper, K.: Aerobics (1968)

(16) Ellinger, F.: The Biologic Fundamentals of Radiation Therapy (1941).

(17) Ohkawara, A, et al: "Glycogen Metabolism Following Ultraviolet Irradiation" Journal of Investigative Dermatology (1972).

2.4.25 Tolerance Of Stress Increases. "Does exercise help us to cope with stress? Under stressful conditions, adrenalin is released in our bodies, which may, or may not, be beneficial, depending upon all conditions at the time. Dr. Hans Selye once subjected twenty rats to loud noises, electrical shock, bright lights and general harassment. Half of the rats were exercised vigorously and were in good health at the end of ten months. The other ten rats which had not been exercised had all died (18)."

"The psychological effects of training and exercise are beginning to find a prominent place in scientific literature. One study of sixty middle-aged men, showed that after an intensive, four-month physical fitness program, most were significantly more emotionally mature, less guilt-prone, more self-sufficient and more imaginative. Others have reported increasing self-confidence and self-image, ability to tolerate the stresses of daily life, mood elevation, and ability to sleep and relax. Introverts turned into extroverts; personalities changed; and with this change came to ability to overcome faulty living habits such as alcoholism and/or cigarette smoking (15)."

"Those who have had experience with the beneficial effects of sunlight, say tht it not only improves the general health, but it also stimulates the appetite, gives a feeling of well-being, and enables one to sleep at night. Somehow, exposure to sunlight has a more relaxing effect upon patients than simply lying down and resting (19). Animals that have been exposed to sunlight havebeen found to have more adrenalin in their adrenal glands. Researchers have assumed that this is beneficial in helping the animals overcome stressful situations (20)."

(18) Selye, H.: The Stress of Life (1956).

(19) Lorincz, A.: "The Physiological and Pathological Changes in Skin from Sunburn and Suntan" JAMA (1960).

(20) Gabovich, R., et al: "Effect of Ultraviolet Radiation on Tolerance of the Organism to Chemical Substances" Vestn Akad Med Nauk SSSR (1975).

2.4.26 <u>Sunlight And Exercise Better Than Exercise Alone</u>. "The fear of heart disease may be the major motivating factor in stimulating people to exercise - and for good reason. It has been known for some time that exercise converts abnormal electrocardiograms to normal ones (22, 23)."

"And a study of the results of combined sunlight and exercise, showed that a group that was getting the sunlight treatmens with exercise, had improved almost twice as much, as shown by their electrocardiograms, as had those who had only exercised, even though both groups were on a general health resort treatment program (24)."

"In one study of college men at the University of Illinois, ultraviolet light treatments were given to half the members of a physical education class. The experiment ran for ten weeks, and at the end of the period, the group that was receiving ultraviolet light had increased their performance on the physical fitness test by almost 20%, while the group that did not receive the ultraviolet light improved by only 1%. There wee only half as many colds in the group that was receiving ultraviolet

light and their blood pressures showed a distinct decrease. The group taking the ultraviolet light treatments showed a greater interest in their class work and attended more regularly. The generally felt they had received a great deal of help from the ultraviolet light treatments (25)."

"It has been shown in other studies that a continuous, low-intensity ultraviolet exposure of school children, applied by means of a special ultraviolet illumination system, markedly increased physical fitness scores among the children. This effect was most apparent during the winter and spring months. The children, who did not receive the extra ultraviolet light during the winter time, had significant increases in their physical fitness scores during the summertime when they, too, received more ultraviolet light from natural sources (26)."

"Sunlight is beneficial to athletes in training, for it not only aids in the conditioning program, but it also strengthens the athletes' resistance to disease. Because an athlete in training is stressing his body to its maximum, his resources to fight infections such as colds and flu may at times be small. The maintenance of a strong immune response can be realized during training with consistent exposure to sunlight, as shown in a study done at the University of Illinois (25)."

- (22) Mikhailov, V.: "Influence of Graduated Sunlight Baths on Patients with Coronary Atherosclerosis" Soviet Medicine (1966).
- (23) Kidera, G.: "Exercise Aids in converting ECG to Normal" JAMA (1968).
- (24) Goldman, A., et al: "Effects of Continuous and Impulse Ultraviolet Radiation Therapy in Clinical Health Resort Treatment of Patients with Hypertension and Chronic Coronary Insufficiency" Vop Kurort Fizioter (1972).
- (25) Allen & Cureton: "Effect of Ultraviolet Radiation on Physical Fitness" Archives of Physical Medicine (1945).
- (26) Ronge, H.: "Ultraviolet Irradiation with Artificial Illumination" Acta Physiology Scandinavia (1948).
- 2.4.27 S.M.A.R.T. "It should be emphasized that, in order to achieve the 'training effect' associated with exercise a gradual and consistent exercise program must be maintained over a period of months. To achieve this 'training effect' from sunlight, a similar gradual and consistent exposure to sunlight must be maintained."

ISTN agrees with Dr. Kime in this last remark and believes that Sensible, Moderate, Appropriate and Responsible Training will help achieve and maintain a state of optimum physical conditioning and Sensible, Moderate, Appropriate and Responsible Tanning will help achieve and maintain a state of optimal photo-protective pigmentation.

#### 2.4.28 Vitamin D Related Benefits Of UV Exposure

Vitamin D From Sunlight Is Best! In one study done in England it appeared that vitamin D obtained from the skin's exposure to the sunlight was far superior to thatobtained from oral ingestion. When over 100 patients were studied as to their intakes of vitamin D, and also as to the individual exposure to sunlight, there seemed to be a direct relationship between the amount of calcium and phosphorous in the blood stream and the amount of exposure to sunlight. The more sunlight a patient received, the higher and more normal would be his levels of calcium and phosphorous, and correspondingly, his bones would be more nearly normal. The amount of vitamin D in the diet of these patients did not seem to be related to the levels of calcium and phosphoreus in the blood stream. The researchers felt that even slight sunlight exposures may be sufficient to help in the prevention of a most serious bone disease, and that 'many old people may be in a stage of biochemical osteomalacia' because of sunlight lack' (27).

A study of veterans who lived in the Chelsea, Massachusetts, Soldiers' Home was done to determine whether extra sunlight would help them to absorb more calcium from their food. The men lived indoors and the study was done during the winter months so that they would not be getting any sunlight. They were given dairy products in their diets and probably got around 200 IU/day of vitamin D. One-half of the men were placed in an environment where they were given more ultraviolet light by using a full spectrum flourescent lighting system. The men were then tested to see how much calcium they wee absorbing. In the group that was not getting the extra ultraviolet light, the amount of calcium absorption decreased by 25%, while the group that was getting the extra ultraviolet light increased their calcium absorption by 15% (28). This study shows that sunlight is more important than dietary vitamin D and is necessary for proper calcium absorption.

"To obtain a protective dose of vitamin D from the sun, one has only to expose a small amount of skin to the sun for a few minutes during the middle of the day during the summer months."

"A toxic reaction has never been shown to occur from the vitamin D produced by the sun (29). Excess amounts of vitamin D achieved on one day's exposure are stored in the liver to be drawn on if exposure is not consistent."

(27) Hodkinson, H. et al: "Sunlight, Vitamin D and Osteomalacia in the Elderly" Lancet (1973).
 (28) Neer, R. et al: "Stimulation by Artificial Lighting of Calcium Absorption in Elerly Human Subjects" Nature (1971).

(29) Blois, m.: "Vitamin D, Sunlight and Natural Selection" Science (1968).

2.4.29 <u>Prevention of Rickets</u>. Hess and Unger published an article "Cure of infantile rickets by sunlight" in 1921 in the *Journal of the American Medical Association*. After this report, mothers ensured their children's health by exposing them to sunlight.

2.4.30 Prevention of Myocardial Infarction. Scragg, et al stated in the abstract to their paper "Myocardial Infarction is Inversely Associated with Plasma 25-Hydroxymitamin D3 Levels: A Community-Based Study" (published in the International Journal of Epidemiology in 1990) that, "The relation between the plasma level of 25-hydroxyvitamin D3, the main metabolite of sun-induced vitamin D, and myocardial infarction (MI) was investigated in a community-based case-control study. Some 179 MI patients presenting to hospital within 12 hours of onset of symptoms were individually matched with controls by age, sex and date of blood collection. MI patients had significantly lower mean 25-hydroxyvitamin D3 levels than controls (32.0 versus 35.5 nmol/L) with the case-control differences being greatest in winter and spring. The relative risk of MI for subjects with 25-hydroxyvitamin D3 levels equal to or above the median was 0.43 compared to subjects below the median. The decrease in MI risk associated with raised vitamin D3 levels was observed in all seasons. These results provide support for the hypothesis thatincreased exposure to sunlight is protective against coronary heart disease."

2.4.31 <u>Suppression of Hyperparathyroidism</u>. Chel et al pubished a paper in the *Journal of Bone and Mineral Research* that stated in the abstract, "Irradiation with UV-B in the very elderly for a few minutes per day leads to adequate improvement of the vitamin D status. It is as effective as oral vitamin D3 in increasing serum (OH) D and suppressing secondary hyperparathyroidism."

2.4.32 <u>Diabetes</u>. "Inadequate vitamin D status: does it contribute to the disorders comprising syndrome 'X'? by B. J. Boucher that was published in 1998 in the *British Journal of Nutrition* stated "Those at risk of vitamin D deficiency include the elderly, those living indoors or having a covered-up style of dress, especially dark-skinned immigrants, pregnant women, and these are groups recognized as being at increased risk of diabetes."

2.4.33 Acute Hip Fracture and Osteoporosis. A paper published in the April 28, 1999 issue of JAMA by LeBoff et al titled "Occult Vitamin D Deficiency in Postmenopausal U.S. Women With Acute Hip Fracture" stated in the conclusions that "Postmenopausal community-living women who presented with hip fracture showed occult vitamin D deficiency. Repletion of vitamin D and suppression of parathyroid hormone at the time of fracture may reduce future fracture risk and facilitate hip fracture repair. Because vitamin D deficiency is preventable, heightened awareness is necessary to ensure adequate vitamin D nutrition, particularly in northern latitudes. The data showed that 50% of the patients with hip fractures had deficient vitamin D levels (less than 30.0 nmol/L). The author stated that "Vitamin D is required for efficient absorption of dietary calcium and for normal mineralization of bone" and concluded with the words "Vitamin D deficiency is preventable and heightened awareness is necessary to institute public health programs to ensure adequate vitamin D nutrition in the elderly, particularly in northern latitudes."

Additionally, it is estimated that 25 million Americans suffer from osteoporosis – a disease characterized by a significant loss in bone density. Low levels of vitamin D contribute to the calcium debt that is associated with this disease. According to Boston University research dermatologist Dr. Michael Holick, several studies have reported that between 41 percent and 54 percent of adults over age 50 are deficient in vitamin D. This <u>silent epidemic</u> causes the painful bone disease osteomalacia, as well as exacerbating bone loss, osteoporosis and the risk of fractures.

Holick believes there are an estimated 1 million osteoporosis-related bone fractures annually in the United States – events that can lead to fatal complications in elderly patients.

2.4.34 <u>Breast Cancer</u>. "Vitamin D and Breast Cancer Risk: The NHANES I Epidemiologic Follow-up Study, 1971-1975 to 1992" by Ester M. John et al was published in the May 1999 issue of *Cancer Epidemiology, Biomarkers & Prevention*. Dr. John's case-control study was the first to build upon the already established environmental correlation between breast cancer incidence and sun exposure. The author stated very clearly that:

- "These data support the hypothesis that sunlight and dietary vitamin D reduce the risk of breast cancer."
- "In this cohort analysis, we found that high exposure to sunlight was associated with a 25-65% reduction in breast cancer risk among women whose longest residence was in a state of high solar radiation."
- 2.4.35 <u>Prostate Cancer</u>. "Geographic Patterns of Prostate Cancer Mortality: Evidence for a Protective Effect of Ultraviolet Radiation" by Hanchette and Schwartz was published in *Cancer* in December, 1992. The authors state:
- "These data lend support to the hypothesis that <u>UV radiation may protect against clinical prostate cancer.</u> Viewed in conjunction with other recent data, including those demonstrating a differentiating effect of vitamin D on human prostate cancer cells, these findings suggest that vitamin D may have an important role in the natural history of prostate cancer."

- "Prostate cancer is the most commonly diagnosed non-skin cancer in men in the United States and ranks second only to lung cancer in number of deaths in men."
- "In summary, this study was designed to test the hypothesis of a protective role of UV radiation on the geographic pattern of prostate cancer mortality. We found that the prostate cancer mortality in the contiguous counties of the United States is correlated inversely with UV radiation and exhibits a significant north-south trend. These findings are consistent with previous findings for black and white men at the state level and lend support to the hypothesis of a protective role of UV radiation."
- 2.4.36 Conclusion: This section has listed many of the proven and potential positive effects of ultraviolet light exposure. Many more are not listed. This is a field that is emerging and will attract more research in the future. The only obstacle that has slowed research into the positive effects of ultraviolet light exposure is funding: There are no industries that profit from promoting sunshine except for the fledgling indoor tanning industry. Conversely, many industries benefit from the position that any UV exposure is harmful, and more money is made scaring people out of the sun than will ever be made by the tanning industry.

As more positive effects are explored, a paradigm shift is likely where the public will learn that regular UV exposure is a good thing for those who can develop tans. In light of this inevitability, declaring UV a carcinogen in a categorical fashion would be foolish and counterproductive.

#### 2.5: THE PHOTOPROTECTIVE TAN:

2.5.1 An article by Barbara A. Gilchrest and associates titled "The Pathogenesis of Melanoma Induced by Ultraviolet Radiation" was published in the April 29,1999 issue of *The New England Journal of Medicine* and it deserves to be discussed. First, it provides important evidence to support the photoprotective qualities of both constitutive and facultative pigmentation.

Dr. Gilchrest states that "Melanin has a photoprotective function in the skin, directly absorbing ultraviolet photons as well as reactive oxygen species generated by the interaction of ultraviolet photons with membrane lipids and other cellular chromophores. Within cells, melanin tends to be distributed in supranuclear "caps" that protect the nuclei from injury caused by ultraviolet radiation".

"That melanin provides effective photoprotection is suggested by the fact that poorly melanized skin is far more vulnerable than melanized skin to acute and chronic injury caused by ultraviolet radiation (sunburn and photoaging or photocarcinogenesis, respectively)".

Early in the paper, Dr. Gilchrest stated that "The risk of melanoma is higher in fair-skinned people, especially those with blond or red hair who sunburn and freckle easily, than in people with darker complexions". We agree that phototype I individuals who are genetically incapable of tanning are at greater risk of nonmelanoma and melanoma skin cancers because they lack the photoprotective benefits that darker skin phototypes (and subtypes) have and that facultative pigmentation conveys.

Later on, Dr. Gilchrest states that "The data predict that a <u>high-dose first exposure</u> to the sun after a prolonged period of sun avoidance will cause substantial damage to DNA in melanocytes and keratinocytes, both of which have a relatively low base-line capacity for DNA repair and a low melanin content". It appears that she is still describing phototype I individuals and we agree that they will follow this pattern <u>every time</u> that they are <u>overexposed</u> ("high-dose first exposure") to UVR. We call this the "Groundhog Day Effect" (a reference to the Bill Murray movie, where the title

character experiences the same pattern of events over and over again.) because it so aptly describes this cycle of overexposure, damage and repair. However, "The Groundhog Day Effect" is not relevant to all other skin types, as developing facultative pigmentation reduces the sensitivity of the individual to UVR and enables the individual to "tolerate" higher levels of UVR without developing erythema. For everyone (even phototype I's) there is a level of UVR that can be tolerated without erythema and below this level the term "exposure" or "acceptable exposure" should be used. The term "overexposure" should only be used to describe the reaction that occurs when more than the level of UVR that can be "tolerated" is experienced and erythema is the visible result.

In this paper, Dr. Gilchrest (and in some of her other papers) chooses to describe "tanning" as the visible result of an injury to the skin. We believe that the development of facultative pigmentation or "tanning" is nothing more nor less than the normal response by the body to controlled UVR exposure. Controlled exposure is defined as exposure to UVR that is below the tolerance level (TUVR) for that individual at that point in time. Tanning is a dynamic process that changes over time, depending upon the frequency, the duration and the intensity of the light source used in the tanning session.

The "injury" response that Dr. Gilchrest describes is the <u>automatic</u> first line of defense by the body that occurs when an individual is <u>overexposed</u> to UVR. This automatic and sometimes painful response is known as erythema or "sunburn" and it is the position of ISTN that erythema or "sunburn" should always be avoided.

This article by Dr. Gilchrest could have been titled: "The Advantages of Choosing Parents Who Can Provide You With A Darker Natural Skin Color and The Value of Maintaining Facultative Pigmentation (a "tan") Year-Round If You Want To Reduce Your Relative Risk of Developing Skin Cancer". It could have been sub-titled: "Unfortunately Skin Phototype I's Have No Current Alternative But To Limit Exposure To The Sun and To Use Sunscreen To Try To Compensate For Their Lack Of Constitutive And Facultative Pigmentation".

#### 3.0 CONCLUSION

Listing ultraviolet radiation as a carcinogen would be a mistake when the evidence clearly shows that other factors are involved in the induction of skin cancer, and that the risks are not shared by all skin types and are clearly weighted toward individuals with fair skin who are genetic susceptibility to skin cancer. What's more, it would be a mistake to categorically classify the most natural "substance" known to man as a source of cancer. Therefore, listing UVR as a carcinogen is not warranted.

#### 4.0 CORRECTION

The NTP submission in the U.S. Federal Register April 2, 1999 regarding the possible inclusion of ultraviolet light in the Tenth Annual Report on Carcinogens incorrectly mis-identifies the standard classification of UV categories. We believe that the following classifications should be used:

UVC - wavelengths from 100 to 280 nm.

UVB - wavelengths from 280 to 315 (or 320) nm.

UVA-2 - wavelengths from 315 (or 320) to 340 nm.

UVA-1 - wavelengths from 340 to 400 nm.

Thank you for your attention. If you have any questions about this document, please contact me at 517-784-1772, ext. 12.

Sincerely,



Joseph A. Levy, executive director International Smart Tan Network

Submitted on behalf of the Network's Federal Regulatory Review Committee Don Smith, co-chair Gene Brenner Frank Giordano Robbie Segler